SEP 1 6 2003

K 030846

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Smoothbeam System, which is substantially equivalent to a previously marketed device intended for use in treatment of facial wrinkles.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Calzetta
Date prepared:	June 09, 2003
Trade Name:	Candela Smoothbeam Laser System
Common Name:	Dermatology Laser System
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Predicate Device:	Laser Aesthetics CoolTouch (K022817) and Candela Mid IR Diode Laser System aka Smoothbeam Laser (K022884)

Description:
The Diode laser is a continuous wave, diode medical laser, controlled by an embedded processor, to be used for use in dermatology for treatment of periorbital wrinkles. The laser system operates with a Dynamic Cooling Device, which provides a short burst of cryogen spray during the laser treatment. The laser output energy is delivered via an optical fiber to a hand piece, which produces a circular beam on the skin. The cryogen is delivered via a hose to a nozzle located in the hand piece. The Dynamic Cooling Device functions to cool the skin during the laser treatment minimizing thermal damage to skin during laser treatment and reducing pain associated with laser treatment.

The Candela Smoothbeam system is comprised of a power supply, optical delivery system, software control system and Dynamic Cooling Device.

The Candela Smoothbeam Laser is equipped with safety interlock systems to protect patients and operators. Users of the device make selections from a control panel to regulate operation during treatment.

Testing:
As a laser product, the Smoothbeam Laser is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition, the device conforms to the UL 544 electrical safety standard and the Essential Requirements of the European Union Medical Device Directives.

Safety and Effectiveness information
The Smoothbeam Laser described in this submission is identical to the Smoothbeam laser cleared for the Indications of treatment of periorbital winkles (K013825) and Atrophic acne scars (K022884) Candela believes that no new issues of safety or effectiveness are raised by the introduction to market the Smoothbeam Laser for the treatment of facial winkles.

Summary of Substantial Equivalence:
The indication for use for the treatment of facial wrinkles is based on substantial equivalence to the Cool Touch Laser, which is cleared for use for the treatment of fine lines and wrinkles (K022817). Additionally, the Candela Smoothbeam Laser utilizes the identical or similar operating principles, matches key design aspects, including same spot size, same of similar wavelength and same maximum delivered power as the predicate devices. On this basis, Candela believes that the Candela Smoothbeam Laser System is substantially equivalent to the predicate devices for the same indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 6 2003

Ms. Lorraine Calzetta
Manager, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K030846
Trade/Device Name: Candela Smoothbeam Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 9, 2003
Received: June 20, 2003

Dear: Ms. Calzetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030846

Device Name: Candela Corporation Smoothbeam Laser System

Indications For Use:

The Candela Smoothbeam Laser System is indicated for use in the treatment of facial wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030846